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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,692	04/17/2001	Motokazu Watanabe	43888-098	2364

7590 09/09/2003

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1753

DATE MAILED: 09/09/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,692	WATANABE ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 June 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,4,5 and 11-15 is/are rejected.
- 7) Claim(s) 2,3,6-10 and 16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>18</u>
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

Response to Amendment

1. Applicant's amendment of June 26, 2003 does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed June 26, 2003 have been fully considered but they are not persuasive. With respect to the rejection of claims 1, 4, 5, and 11 under 35 U.S.C. § 103(a) as being obvious over the English language translation of Yoshioka et al. as modified by Akio et al., Applicant argues,

[W]hile Akio discloses potassium gluconate or sodium salts thereof can improve the stability of glucose dehydrogenase, the reference does not specify whether the gluconate is effective for PQQ dependent glucose dehydrogenase. It should be appreciated that PQQ base enzymes have different characteristics and response. The molecular weight and characteristics of an enzyme vary greatly depending on a co-enzyme. Moreover, Akio appears to be directed to enzymes that are immobilized by covalent bonding to some object. Hence, it is respectfully submitted that one of ordinary skill in the art would not have recognized that the teachings of Akio would apply to PQQ based enzymes and, thus, there is no expectation of success. *Page 8 of amendment.*

The examiner respectfully disagrees with Applicant's arguments. While the Akio et al. reference does not mention whether the gluconate is effective for PQQ dependent glucose dehydrogenase, it also does not mention any particular glucose dehydrogenase co-enzyme. This suggests the general usefulness of gluconate for stabilizing various glucose dehydrogenases. In fact, the reference is clear that the enzyme to be stabilized need not be glucose dehydrogenase. Akio et al. teaches the concept of stabilizing an enzyme in a reagent layer by adding the oxidized substrate of the enzyme to reagent layer. Gluconate may be added to a reagent layer comprising

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glucose oxidase or glucose dehydrogenase to stabilize the enzyme. Some other enzymes disclosed as being stabilized by the corresponding oxidized substrate are lactic-acid oxidizing enzyme, lactate dehydrogenase, ascorbate oxidase. See *Technical Problem, Effect of the Invention*, claim 1, paragraph [0015] of *Means*. Thus, barring evidence to the contrary, one with ordinary skill in the art would expect success, that is, improved stability, when gluconate is added to a reagent layer PQQ dependent glucose dehydrogenase.

As for the enzymes in Akio et al. being covalently bonded to some object, this point is moot because Applicant's claims do not exclude having the enzyme covalently bonded to some object. Moreover, Applicant's claim may read on an enzyme covalently bonded to some object. Independent claims 1 and 12 do not require the reagent layer to be on the electrode system as the reagent layer need only be in the vicinity of the electrode system. According to page 15 of the specification, this means that the reagent layer may be attached to the underside of the cover layer. There is strong motivation to covalently attach the enzyme to the underside of the cover layer as taught by Akio et al.: to keep the enzyme from falling from the cover layer to the base substrate.

Status of the Rejections Pending since the Office Action of March 26, 2003

3. All of the previous rejections are withdrawn.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 4, 5, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the newly cited English language translation of Yoshioka et al. (JP 10-227755) in view of newly cited English language translation of Akio et al. (JP 09-262086).

Addressing Claim 1, Yoshioka et al. teach a glucose sensor (paragraph [0009] of the *Detailed explanation of the invention*) comprising an electrically insulating base plate (1); and electrode system including at least a working electrode (4) and a counter electrode (5) formed on the base plate; and a reaction layer (7) containing at least pyrrolo-quinoline quinone dependent glucose dehydrogenase (claim 1), formed in contact or in the vicinity of the electrode system, (Figure 2).

Akio et al. teach adding gluconic acid to a reaction layer containing glucose dehydrogenase so as to enhance the stability of the reaction layer (the abstract; Technical Problem; and paragraphs [0014]-[0016] of *Means*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to add gluconic acid to the reaction containing glucose dehydrogenase as taught by Akio et al. in the invention of Yoshioka et al. because as taught by Akio et al. the stability of an immobilized enzyme can be saved for a long

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period of time (*Effect of the Invention*), thereby preserving the ability of the sensor to make accurate measurements.

Yoshioka et al. also do not mention storing the glucose sensor in a sealed container. Akio et al. also teach storing the sensor in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to store the glucose sensor in a sealed container as taught by Akio et al. in the invention of Yoshioka et al. as modified by Akio et al. because this will further help preserve the reaction layer. The container seal will prevent the reaction layer from being contaminated or wetted.

Addressing Claim 4, Akio et al. disclose using a sodium or potassium salt of gluconic acid in claim 4, for example.

Addressing Claims 5 and 11, Yoshioka et al. disclose suitable electron mediators in paragraph [0006].

Addressing Claim 12, Yoshioka et al. teach a glucose sensor (paragraph [0009] of the *Detailed explanation of the invention*) comprising an electrically insulating base plate (1); and electrode system including at least a working electrode (4) and a counter electrode (5) formed on the base plate; and a reaction layer (7) containing at least pyrrolo-quinoline quinone dependent glucose dehydrogenase (claim 1), formed in contact or in the vicinity of the electrode system (Figure 2).

Akio et al. teach adding gluconic acid to a reaction layer containing glucose dehydrogenase so as to enhance the stability of the reaction layer (the abstract; *Technical Problem*; and paragraphs [0014]-[0016] of *Means*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to add gluconic acid to the reaction containing glucose dehydrogenase as taught by Akio et al. in the invention of Yoshioka et al. because as taught by Akio et al. the stability of an immobilized enzyme can be saved for a long period of time (*Effect of the Invention*), thereby preserving the ability of the sensor to make accurate measurements.

Yoshioka et al. as modified by Akio et al. also do not mention whether “the response of the sensor immediately fabricated is substantially the same as compared to the sensor after being stored in a sealed container for one week at 40°C.” However, Akio et al. teach storing the sensor in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). Furthermore, Akio et al. teach that after 1000 hours of being in a sealed container a glucose oxidase sensor had substantially the same response as before it was stored (presumably after being immediately fabricated). Thus, barring evidence to the contrary, since the glucose sensor claimed by Applicant is structurally and compositionally the same as that taught by Yoshioka et al. as modified by Akio et al. and since Akio et al. teach that the additive can stabilize a reaction layer containing an enzyme so that after 1000 hours of being in a sealed container a sensor had substantially the same response as before it was stored, the sensor taught by Yoshioka et al. as modified by Akio et al. will inherently have the response property claimed.

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Addressing claim 13, Yoshioka et al. as modified by Akio et al. in the rejections of claim 12 do not mention storing the glucose sensor in a sealed container. Akio et al. teach storing the sensor in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to store the glucose sensor in a sealed container as taught by Akio et al. in the invention of Yoshioka et al. as modified by Akio et al. because this will further help preserve the reaction layer. The container seal will prevent the reaction layer from being contaminated or wetted.

Addressing claims 14 and 15, Yoshioka et al. as modified by Akio et al. do not mention having gluconic acid and glucose dehydrogenase within the claimed ranges of amounts; however, barring evidence to the contrary, such as unexpected results the amount of enzyme provided in the reagent layer will be determined largely by (and be proportional to) the expected amount of analyte and the amount of gluconic acid provided in the reagent layer will in turn be determined by (and be proportional to) the amount of enzyme in the reagent layer.

Allowable Subject Matter

6. Claims 2, 3, 6-10, and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter:

- a) Claim 2: the combination of limitations requires that the reaction layer contain an additional additive to gluconic acid selected from the Markush group of claim 2;
- b) Claim 3: Yoshioka et al. as modified by Akio et al. only teach alkali metal ions, such as potassium and sodium;
- c) Claims 6, 7, and 9 depend from allowable claim 2;
- d) Claims 8 and 10 depends from allowable claim 3; and
- e) Claim 16 is original claim 1 with original claim 2 incorporated, which was previously indicated to be allowable.

Final Rejection

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8.30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
Alex Noguerola
9/05/03